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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,288	04/27/2000	Edward Nathaniel Hanley JR.	8151-24A	3083

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/560,288	HANLEY ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35 and 37-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35 and 37-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The amendment filed on 8/03/04 has been entered. It is again noted that no interference can be declared until claims are found allowable.

2. The rejection of claims 53-56 & 58 under 35 U.S.C. 102(a) as being anticipated by Chelberg et al is withdrawn due to the cancellation of these claims.

3. The rejection of claims 35, 37-38 & 47-51 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is withdrawn due to Applicants' arguments after the amendment of the claims.

4. Applicants' arguments filed 8/03/04 have been fully considered but they are not deemed to be persuasive.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claim 35 is objected to because of the following informalities: claim 35(e) no longer recites "said carrier". Appropriate correction is required. It is further suggested that Applicants re-read their claims for proper basis for any other "said" recitations.

7. The Gruber Declaration under 37 CFR 1.132 filed 8/03/04 is insufficient to overcome the rejection of the pending claims rejected for lack of enablement as set forth in the last Office action because it is immaterial whether parent application (now U.S. Patent 6,080,579) was directed to "propagating human intervertebral disc cells", because this application is alternatively directed toward "*treating* human disc diseases" [emphasis added]. Second, what a single dependent claim recites (i.e., claim 48), or does not recite, does not dictate what the other recited claims encompass; especially when Declarant is improperly reading claim limitations not present within that currently claimed. In other words, the claims are not directed to a method of implanting disc cells, which reasonably would be enabled, but alternatively encompass treating human neurodegenerative disc disease states, which currently have no known treatment, and wherein the mere statement that the instant invention overcomes that not currently accepted within the art (i.e., as illustrated by Guilak et al., Aigner et al, Frick et al., and Luk et al. previously made of record), is not reasonably supported by the paucity of guidance provided within the instant specification, for the reasons extensively made of record. In regards to Declarant's arguments concerning "annulus and/or cells", this issue is now moot due to the amendment of the claims to remove this unnecessary and otherwise inconsistent claim language (i.e., which was initially made of issue by Applicants themselves on page 3 in their 6/10/02 response). Lastly, what Declarant's "opinion", or "feelings", entail does not reasonably obviate the pending *prima facie* lack of enablement for *that claimed*, for the reasons extensively made of record (especially as it relates to the structural and mechanical requirements that reasonably must be overcome to enable a "treatment", as currently claimed), and because not a single *in vivo*

publication illustrating treatment of any human disc disease is recited within Declarant's CV to redefine the state of the art at the time of filing the instant application. In summary, Declarant's arguments are not on point, and unfortunately assume limitations not claimed. Thus, this declaration is not persuasive for the reasons made of record in the previous Office actions.

It is noted that amending claim 35 (and claim 48) to "a method of implanting human intervertebral disc cells into a patient with damaged or diseased intervertebral disc tissue..." should obviate the pending rejection under 35 U.S.C. 112, first paragraph; consistent with Declarant's arguments.

8. Claims 35 & 37-51 stand are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using therapeutic compositions for implanting early childhood human intervertebral disc cells and a carrier that contain required and defined cell stimulants/growth factors/carrier molecules to aid in the treatment of human disc diseases or injuries, does not reasonably provide enablement for treatment methods that encompass treating neurodegenerative disc disease states, which currently have no known treatment, or by using cells that no longer developmentally exist, or for compositions missing required/ defined components or comprising carrier derivatives thereof (i.e., in that none of the claims recite each and every required component). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper NOs: 3 (mailed 9/13/00), 7 (mailed 5/09/01), 16 (mailed 5/21/02), 22 (mailed 10/16/03) and 20040510, and as follows.

In contrast to Applicants' arguments on pages 6-8 of the response, the issue remains that the current claims would not reasonably work in bipedal human animals, for the reasons previously made of record, and as argued above. In summary, the type of matrix made by disc cells is dependent on the environment these cells are placed within and on the type of disc cells used, which the claims fail to fully define. Again, as previously made of record, disc cells are a heterogeneous population of cells with different intrinsic variations in their responses to *mechanical stimuli*, with distinct biosynthetic capabilities, wherein what constitutes a successful regenerative processes is unclear within the art (i.e., in that the claims encompass neuronal regeneration and/or a sufficient matrix to reasonably withstand the mechanical forces necessitated in a biped human when upright), and in which the instant specification fails to provide guidance toward overcoming these intrinsic problems in generating a potential successful "treat[ment of] human disc diseases". In other words, one skilled within the art would not know how to use the currently claimed invention in a treatment, when a treatment would not reasonably be expected to succeed when such matrixes/implanted disc cells collapse upon themselves, thereby, destroy neural pathways, and resulting in paralysis once a patient attempts to become upright.

It is noted that amending claim 35 (and claim 48) to "a method of implanting human intervertebral disc cells into a patient with damaged or diseased intervertebral disc tissue..." should obviate the pending rejection under 35 U.S.C. 112, first paragraph; consistent with Applicants' arguments.

9. Claims 42-43, 46 & 47-51 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No: 22 (mailed 10/16/03) and 20040510, and as follows.

No proper antecedent basis now exists for the recitation of "said disc cells" in claim 47, in which it is unclear again what exact cells are being referenced, because many different disc cells are recited in claims 41 & 39. For example, "human intervertebral disc cells", "cultured human intervertebral disc cells", "diseased or injured disc cells" and "live intervertebral disc cells" are all being recited in this claim. Note further that although "cultured intervertebral disc cells" exist in base claim 39, no "cultured *human* intervertebral disc cells" exist; thereby, not having improper antecedent basis (i.e., as it relates to claim 42).

The new recitation of "debriding diseased or injured disc cells" in claim 46 makes little sense because cells are not "injured" or "diseased", unlike "tissue". It is suggested that amending this claim back to that originally recited should obviate this particular rejection. However, again proper antecedent basis would then be required for any "said disc tissue".

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
October 14, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER

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